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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,731	02/19/2008	Bakulesh Mafatlal Khamar	21059/0206949-us0	8375
7278	7590	06/25/2008	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			SWARTZ, RODNEY P	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,731	<b>Applicant(s)</b> KHAMAR ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20June2006.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-26 and 29 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-26 and 29 is/are rejected.  
 7) Claim(s) 1-3-17,22-26 and 29 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 20June2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 20 June 2006, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, and 29 have been amended. Claims 27 and 28 have been canceled.
2. Claims 1-26 and 29 are pending and under consideration.

**Specification**

3. The disclosure is objected to because of the following informalities:

Page 2, line 17, "peptider" should be "peptides", "poly peptides" should be "polypeptides"; line 19 what is meant by "antigen can be encoded into nucleic acids".

Page 3, line 5, "class i" should be "class I"; line 17, "Bacteria" should be "bacteria"; line 26, "does not" should be "do not".

Page 4, line 16, delete the comma immediately following "adjuvant", "Aluminum" should be "aluminum"; line 17, "(alum) have" should be "(alum) and has"; line 24, "Sponin" should be "saponin".

Page 5, line 8, "a oil" should be "an oil"; line 11, "CFA. e.g.," should be "CFA, e.g.,"; line 20, what is in space between "alanine-2" and "(1"?

Page 6, line 10, "S. frugiperda" should be in italics; line 20, what is meant by "ace mannan"?

Page 7, line 9, "It is long" should be "It is a long".

Page 10, lines 7, 9, 11, 13 "Mycobacterium w" should be in italics; line 18, "Mw" should be in italics"; line 25, what is meant by "antigen encoded in nucleic acids"; line 28, what is meant by "adjuvant and adjuvant to containing compositions".

Page 11, lines 2, 4, 6, 9, 10, 12, 14, 17, 19, 21, 22, "Mw" should be in italics.

Page 12, line 2, "Mw" should be in italics; lines 4, 5, "Mycobacterium w" should be in italics; Line 9, "sautn's" should be "sauton's"; line 11, "middle brook" should be "Middlebrook"; line 12, "Glucose" should be "glucose", "Bovine" should be "bovine"; line 13, "there off" should be "there of"; line 20, "and leave as" should be "and left as"; line 27, "middlebrook" should be "Middlebrook".

Page 13, line 8, "palletisation" should be "pelletization".

Page 14, line 4, "test.: " should be "test: "; line 7, "balb/c" should be "Balb/c"; line 21, "Mycobacterium w" should be in italics; line 24, "ingredient" should be "gradient"; line 25, "re-pelted" should be "repelleted"; line 29, "there off" should be "thereof".

Page 15, lines 10, 18, "Mycobacterium w" should be in italics; line 18, "Middle brook" should be "Middlebrook"; lines 23, 25, "Mw" should be in italics.

Page 16, line 2, "Mw" should be in italics; line 7, "preimmunised" should be "preimmunized"; line 12, "Elisa" should be "ELISA"; line 15, "using" and "adjuvant" should not be in italics.

Page 17, line 7, what is meant by "base live"; line 9, what is meant by "with days on 0"; line 26, "Mw" should be in italics; line 27, "were bleed" should be "were bled".

Page 18, line 8, "In each groups" should be "In each group"; line 19, "Value" should be "value".

Page 19, lines 6, 7 "Mw" should be in italics; line 16, "Elisa" should be "ELISA"; line 19, "Intra dermal" should be "intradermal"; line 21, "mcG" should be "mcg".

Page 20, line 10, "adults" should be "adult"; line 11, "Intra muscular" should be "intramuscular"; line 22, "mw" should be "Mw".

Page 21, line 1, "were bleed" should be "were bled"; line 2, "concavaline A" should be "concanavalin A"; lines 10, 23, "mw" should be "*Mw*"; line 11, "ca -19.9" should be "CA-19.9"; line 18, "concavaline A" should be "concanavalin A".

Page 22, lines 1, 16, "were bleed" should be "were bled"; line 2, "concavaline A" should be "concanavalin A"; line 3, "Hrs" should be "hrs"; lines 9, 24, "mw" should be "*Mw*"; line 25, "*Salmonella typhi*" should be in italics.

Page 23, lines 1, 18, "were bleed" should be "were bled"; lines 2, 19, "concavaline A" should be "concanavalin A"; lines 3, 20, "Hrs" should be "hrs"; line 10, "mw" should be "*Mw*"; line 25, "kind" should be "kinds".

Page 24, line 6, "one moth" should be "one month".

Appropriate correction is required.

### **Drawings**

4. Figure 1 is objected to because: "Neutralising" should be "Neutralizing"; *Mw* should be *Mw* in title.
5. Figure 2 is objected to because: "Neutralising" should be "Neutralizing"; *Mw* should be *Mw* in title.
6. Figure 3 is objected to because: *Mw* should be *Mw* in title.
7. Figure 4 is objected to because: two instances of "immunisation" should be "immunization"; *Mw* should be *Mw* in title.
8. Figure 5 is objected to because: "immunisation" should be "immunization"; *Mw* should be *Mw* in title.
9. Figure 6 is objected to because: "immunisation" should be "immunization"; *Mw* should be *Mw* in title.

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10. Figure 7 is objected to because: Mw should be *Mw* in title.
11. Figure 8 is objected to because: "immunisation" should be "immunization"; Mw should be *Mw* in title.
12. Figure 9 is objected to because: "immunisation" should be "immunization"; Mw should be *Mw* in title.
13. Figure 10 is objected to because: "Antibody" should be "antibody" in title; "immunisation" should be "immunization"; Mw should be *Mw* in title.
14. Figure 11 is objected to because: Mw should be *Mw* in title.
15. Figure 12 is objected to because: "immunisation" should be "immunization"; Mw should be *Mw* in title.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### **Claim Objections**

16. Claims 1, 2-16, and 29 are objected to because of the following informalities: all occurrences of "Mycobacterium w" should be in italics. Appropriate correction is required.
17. Claim 7 is objected to because of the following informalities: "ingredient" should be "gradient". Appropriate correction is required.
18. Claim 17 is objected to because of the following informalities: in line 5, "antigen" should be "antigens". Appropriate correction is required.
19. Claim 25 is objected to because of the following informalities: line 3, "mortality" should be "mortality". Appropriate correction is required.
20. Applicant is advised that should claim 1 be found allowable, claims 22-26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-17,22-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/049667).

Claim 1 is drawn to a composition comprising *Mycobacterium w* or its constituents in a pharmaceutically acceptable carrier. Claim 2 is the same composition further comprising other

adjuvants. Claims 3-17 are dependent from claim 1 and are recitations of methods of preparation of the whole *Mycobacterium w* or its constituents. Claims 22-26 and 29 are dependent from claim 1 and are drawn to intended usage of the composition and therefore do not place any patentability to the compositions.

Khamar et al teach the claimed compositions of whole *Mycobacterium w* and its constituents and the methods of obtaining the compositions (Abstract; page 4; Examples 1-6; claims 2-15, 26-30, 36).

22. Claims 1-17,22-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/075825).

Claim 1 is drawn to a composition comprising *Mycobacterium w* or its constituents in a pharmaceutically acceptable carrier. Claim 2 is the same composition further comprising other adjuvants. Claims 3-17 are dependent from claim 1 and are recitations of methods of preparation of the whole *Mycobacterium w* or its constituents. Claims 22-26 and 29 are dependent from claim 1 and are drawn to intended usage of the composition and therefore do not place any patentability to the compositions.

Khamar et al teach the claimed compositions of whole *Mycobacterium w* and its constituents and the methods of obtaining the compositions (Abstract; page 3, line 1 to page 5, line 6; Examples 1-4; claims 10-20, 23-25, and 33).

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim does not end with a period. Therefore, the claim is indefinite concerning what is the limits of the claim.

24. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the modifier "preferably" makes the claim indefinite because it is unclear if "water insoluble" is actually a criticality being claimed.

25. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the metes and bounds of the term "resembling".

26. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 contains the trademark/trade name TWEEN 80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

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A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe solvent and, accordingly, the identification/description is indefinite.

In addition, the claim recites that *Mycobacterium w* does not hydrolyse TWEEN 80. It is unclear what is meant by this recitation that a bacterium hydrolyzes TWEEN 80.

27. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by an antigen encoded "in" nucleic acids.

28. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the metes and bounds of the term "derived". The specification does not define the term. It is recommended that "isolated from" or "purified from" be utilized.

29. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from rejected claims.

### **Conclusion**

30. No claims are allowed.

31. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 10, 2008